pharmaceutically acceptable salt thereof is from 10 mg to 1200 mg.

34. (New) The pharmaceutical composition according to claim 28, wherein the amount of S-tofisopam, prodrug, or a pharmaceutically acceptable salt thereof is from 50 mg to 600 mg.

35. (New) The pharmaceutical composition according to claim 29, wherein the amount of S-tofisopam, prodrug, or a pharmaceutically acceptable salt thereof is from 100 mg to 400 mg.

REMARKS

Applicants request acceptance of the claims of the present application in view of the above amendments and the following remarks.

OBJECTIONS

As requested by the Examiner, the following statement has been incorporated at the beginning of the specification: "This application is a continuation of application Serial No.

10/008,516, filed November 8, 2001, now US Patent No. 6,649,607."

As requested by the Examiner, Applicants have amended claims 30-32 to overcome the Examiner's objections.

REJECTIONS

Claims 28 and 29 have been rejected under 35 U.S.C. 102(a) as being anticipated by the Landry et al reference. The Landry reference teaches the use of (R)-tofisopam for the prevention and treatment of anxiety and anxiety disorders. (R)-tofisopam was found to be the active isomer of racemic tofisopam in the head twitch assay described in column 21, lines 24-34. (S)-tofisopam was used in the assay merely to show that the (S)-enantiomer was inactive in the assay. Thus, the Landry reference does not anticipate, teach or suggest the present invention which describes (S)-tofisopam as an active pharmaceutical ingredient which can be used to effectively treat a disease.

Claims 1-5 have been cancelled. Claim 28 has been amended to delete the oral administration method while retaining the intraperitoneal, subcutaneous, intranasal,

intramuscular, intrathecal, sublingual, rectal, intravenous and transdermal delivery options. The Landry reference does not anticipate these delivery methods. Nor does the Landry reference teach or suggest that S-tofisopam could be administered by these methods.

Furthermore, the amendment to claim 29 deletes the language "approximately". As the Examiner pointed out in the communication dated August 16, 2004, the Landry reference describes the administration of S-tofisopam at 30 mg/kg in rats. This would correspond to a dosage of 7.5 mg to 9 mg of S-tofisopam. Amending claim 29 to delete "approximately" establishes that the doses considered are above the dose range disclosed. The Landry reference does not anticipate claim 29. Nor does the Landry reference teach or suggest the use of doses of 10 mgs or greater of tofisopam, because the use of S-tofisopam at 7.5 mg to 9 mg was not effective.

Applicants have added additional claims dependent on claim 29 to cover the different dose ranges.

None of these amendments introduces new matter.

Applicants kindly request that the claims be accepted in view of the remarks and amendments provided above.

Respectfully submitted,

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CLAIMS WITH MARKUPS

1. (Canceled) A composition comprising a therapeutically effective amount of S-tofisopam, a prodrug or pharmaceutically acceptable salt thereof, substantially free of its R-enantiomer, with a pharmaceutically acceptable carrier.

2. (Canceled) The composition of claim 1 wherein the amount of S-tofisopam or a prodrug or a pharmaceutically acceptable salt thereof is 85% or more by weight of the total weight of tofisopam.

3. (Canceled) The composition of claim 1 wherein the amount of S-tofisopam or a prodrug or a pharmaceutically acceptable salt thereof is 90% or more by weight of the total weight of tofisopam.

4. (Canceled) The composition of claim 1 wherein the amount of S-tofisopam or a prodrug or a pharmaceutically acceptable salt thereof is 95% or more by weight of the total weight of tofisopam.

5. (Canceled) The composition of claim 1 wherein the amound of S-tofisopam or a prodrug or a pharmaceutically acceptable salt thereof is 99% or more by weight of the total weight of tofisopam.

6. (Canceled) The composition according to claim 1, wherein the conformation of the S-tofisopam is 80% (-) and 20% (+).

7. (Canceled) The composition according to claim 1 further comprising another anti-convulsant.

8. (Canceled) The composition according to claim 7, wherein the other anti-convulsant is a benzodiazepine.

9. (Canceled) The composition according to claim 7, wherein the other anti-convulsant is a 1,4-benzodiazepine.

10. (Canceled) The composition according to claim 7, wherein the other anti-convulsant is selected from the group consisting of diazepam, lorazepam, clonazepam, clorazepate and nitrazepam.

11. (Canceled) The composition according to claim 1, wherein said composition is a controlled-release pharmaceutical composition.

12. (Canceled) A method of treating convulsions or seizures comprising administering to a subject in need of treatment therefore, a therapeutically effective amount of the composition of claim 1.

13. (Canceled) A method of preventing convulsions or seizures in a subject at risk for developing convulsions or seizures comprising administering to a subject in need of treatment therefore, a therapeutically effective amount of the composition of claim 1.

14. (Canceled) The method according to claim 12 or 13 wherein the subject is a human.

15. (Canceled) The method according to claim 12 or 13 wherein the amount of S-tofisopam or a prodrug or a pharmaceutically acceptable salt thereof is 90% or more by weight of the total weight of tofisopam.

16. (Canceled) The method according to claim 12 or 13 wherein the amount of S-tofisopam or a prodrug or a pharmaceutically acceptable salt thereof is 95% or more by weight of the total weight of tofisopam.

17. (Canceled) The method according to claim 12 or 13 wherein the amount of S-tofisopam or a prodrug or a pharmaceutically acceptable salt thereof is 99% or more by weight of the total weight of tofisopam.

18. (Canceled) The method according to claim 12 or 13, wherein the composition according to claim 1 is administered together or sequentially with another anticonvulsant.

19. (Canceled) The method according to claim 18, wherein the other anti-convulsant is a benzodiazepine.

20. (Canceled) The method according to claim 18, wherein the other anti-convulsant is a 1,4-benzodiazepine.

21. (Canceled) The method according to claim 18, wherein the other anti-convulsant is selected from the group

consisting of diazepam, lorazepam, clonazepam, clorazepate and nitrazepam.

22. (Canceled) The method according to claim 12 or 13, wherein the composition is administered intraperitonealy, subcutaneously, intranasally, intramuscularly, intrathecaly, sublingualy, rectally, by intravenous infusion, transdermal delivery or orally as a tablet, a capsule or a liquid suspension.

23. (Canceled) The method according to claim 12 or 13, wherein the amount of S-tofisopam, prodrug, or a pharmaceutically acceptable salt thereof administered is from approximately 10 mg to 1200 mg.

24. (Canceled) The method according to claim 23 wherein the amount of S-tofisopam, prodrug, or a pharmaceutically acceptable salt thereof administered is from approximately 50 mg to 600 mg.

25. (Canceled) The method according to claim 23 wherein the amount of S-tofisopam, prodrug, or a pharmaceutically acceptable salt thereof administered is from approximately 100 mg to 400 mg.

26. (Canceled) The method according to claim 12 or 13 wherein said amount is administered in 1 to 4 doses per day.

27. (Canceled) The method according to claim 26 wherein said amount is administered in 1 to 2 doses per day.

28. (Currently amended) A [The] pharmaceutical composition comprising a therapeutically effective amount of S-tofisopam, a prodrug or pharmaceutically acceptable salt thereof, substantially free of its R-enantiomer, with a pharmaceutically acceptable carrier, [according to claim 1,] wherein the composition is for intraperitoneal, subcutaneous, intranasal, intramuscular, intrathecal, sublingual, rectal, intravenous infusion, or transdermal delivery [or oral administration].

29. (Currently amended) A [The] pharmaceutical composition comprising a therapeutically effective amount of S-tofisopam, a prodrug or pharmaceutically acceptable salt thereof, substantially free of its R-enantiomer, with a pharmaceutically acceptable carrier [according to claim 1], wherein the amount of S-tofisopam, prodrug, or a pharmaceutically acceptable salt thereof is from ~~approximately~~ 10 mg to 1200 mg.

30. (Currently amended) The pharmaceutical composition of claim 29, comprising a therapeutically effective amount of S-tofisopam, a prodrug or pharmaceutically acceptable salt thereof, substantially free of its R-enantiomer, with a pharmaceutically acceptable carrier [according to claim 1], wherein the amount of S-tofisopam, prodrug, or a pharmaceutically acceptable salt thereof is from 50 mg to 600 mg.

31. (Currently amended) The pharmaceutical composition of claim 29, comprising a therapeutically effective amount of S-tofisopam, a prodrug or pharmaceutically acceptable salt thereof, substantially free of its R-enantiomer, with a pharmaceutically acceptable carrier [according to claim

1], wherein the amount of S-tofisopam, prodrug, or a pharmaceutically acceptable salt thereof is from 100 mg to 400 mg.

32. (Currently amended) A method of administering a pharmaceutical comprising a therapeutically effective amount of S-tofisopam, a prodrug or pharmaceutically acceptable salt thereof, substantially free of its R-enantiomer, with a pharmaceutically acceptable carrier, comprising preparing the pharmaceutical composition comprising S-tofisopam, pro-drug or pharmaceutically acceptable salt thereof and a pharmaceutically effective carrier and administering the pharmaceutical composition at a dose of less than 30 mg/kg.

33. (New) The pharmaceutical composition according to claim 28, wherein the amount of S-tofisopam, prodrug, or a pharmaceutically acceptable salt thereof is from 10 mg to 1200 mg.

34. (New) The pharmaceutical composition according to claim 28, wherein the amount of S-tofisopam, prodrug, or a

pharmaceutically acceptable salt thereof is from 50 mg to 600 mg.

35. (New) The pharmaceutical composition according to claim 28, wherein the amount of S-tofisopam, prodrug, or a pharmaceutically acceptable salt thereof is from 100 mg to 400 mg.